REMARKS/ARGUMENTS

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claim 1 has been amended to define more clearly the patentable invention applicants believe is disclosed herein. In particular, claim 1 has now been amended to incorporate limitations from dependent claims 3 and 9 (now cancelled). Accordingly, the monitoring system defined by claim 1 now requires that the claimed graphic include a visual indicator for correcting the improper connection and that the sensed pressure associated with an improper connection with the device is lower than a pressure value associated with a proper connection with the device. Claims 4-8 are unchanged by the present amendment paper, and claim 2 was previously cancelled. It is submitted that the present claim amendments do not raise new issues, and thus are proper for entry after-final. The applicants respectfully request that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

The Examiner has combined four (4) references in rejecting claims 1 and 3-9 under 35 U.S.C. 103(a). In particular, the Examiner has cited U.S. Patent No. 5,761,069 to Weber et al. as the primary reference, and has cited U.S. Patent No. 6,485,684 to Mapson et al., U.S. Patent Application Publication No. 2004/0091389 to Malkin et al., and U.S. Patent No. 5,279,799 to Moser et al., as secondary references. It is respectfully submitted that the applicants' invention is not obvious in view of the combined teachings of the foregoing references, as will be discussed in detail herein.

Weber et al.

The Examiner argues that Weber et al. teach a system for monitoring fluid circulation in a reprocessor apparatus for sterilization where there are fluid connections, wherein the monitoring system comprises a pressure sensor for sensing a pressure and generating an electrical signal indicative of a sensed pressure, and a controller responsive to the electrical signal. The Examiner points out that the pressure sensed by the pressure sensor is indicative of a failed circulation pump, but that Weber et al. *fail to teach the importance of insuring the connections within the reprocessing system are secure*.

The applicants acknowledge that Weber et al. teach a pressure sensor 250 that is used to read water pressure at the output end of an oscillating pump 246. In the event that no water pressure is detected by pressure sensor 250 during a wash step 133, *such as in the case where the oscillating pump 246 fails*, pressure sensor 250 acts to close down system 10. It is important to note with reference to FIG. 13 of Weber et al. that pressure sensor 250 is disposed between oscillating pump 246 and an external manifold 117 comprising a plurality of ports 121. A first end of tubing segments 132a-132c are respectively connected to output ports 121 of manifold 117 and a second end of tubing segments 132a-132c are connected to respective ports of a scope 84, as best seen in FIG. 12 of Weber et al. Since pressure sensor 250 is located *upstream* from manifold 117, pressure sensor 250 is not used to provide an indication of the pressure at the connections with the ports of scope 84. Weber et al. merely teaches sensing the pressure at the output end of oscillating pump 246 *in order to detect whether oscillating pump 246 has failed.* It is respectfully submitted that nowhere does Weber et al. teach or suggest the use of a pressure sensor in determining whether a proper connection has been made between a fluid circulation system and a device being microbially deactivated. Pressure sensor 250 taught by Weber et al. functions as a means for detecting failure of the oscillating pump 246 used to pump water to a manifold 117.

The Examiner has acknowledged that Weber et al. only teach that pressure sensor 250 senses a pressure indicative of a failed circulation pump, and that "Weber et al. fail to teach the importance of ensuring the connections within the reprocessing system are secure."

Mapson et al.

The Examiner relies upon Mapson et al. for the teaching that "when improper connections are made between sterilant tubes and medical instruments, assurance that the sterilant is contacting all microorganism in the lumens is lost, leaving the instrument contaminated." The Examiner further relies upon Mapson et al. in support of the teaching of "using a leak detector in the reprocessing system to determine if the *lumen* is holding a preselected vacuum or positive pressure" (emphasis added). The Examiner concludes that Mapson et al. show "the importance of having a fully pressurized system to expose all

microorganisms to sterilant and ensuring certain parts of instruments are not contacted by fluids. A decrease in fluid pressure in the system would be evidenced by an improper connection."

The applicants acknowledge that Mapson et al. recognize the importance of selecting the proper fittings or plugs and making proper connections between the fluid supply, fittings and lumens. It is also acknowledged that Mapson et al. recognize that when improper fittings or plugs are used or when improper connections are made, the assurance that the anti-microbial agent is contacting all microbes within the lumens is lost. However, it is respectfully submitted that Mapson et al. do not teach or suggest pressure level detection as a means for determining whether proper fittings or plugs have been selected or whether proper connections have been made between fluid supply, fitting and lumens. Instead, Mapson et al. teaches a method and apparatus that does not utilize fluid pressure or sensing devices of any kind to determine whether proper fittings or plugs have been used or whether proper connections have been made, as will be discussed in detail below.

Mapson et al. recognize that endoscopes have a plurality of *lumens* that may have different cross-sections, length, internal obstructions, and alike, and that it is advantageous to supply fluid to different lumens of the endoscope at different pressures. Mapson et al. also note that endoscopes often have a lumen that does not need to be sterilized, or that can be damaged by contact with certain fluids. Mapson et al. also note that lumens have a variety of connector styles such as screw threads, bayonet pipe connectors, and alike as well as different diameters.

It is respectfully submitted that Mapson et al. fail to teach or suggest the use of a pressure sensor or a fluid pressure as a means for detecting an improper connection. While the Examiner has noted that Mapson et al. teaches using a leak detector to determine if a *lumen* is holding a preselected vacuum or positive pressure, the leak detector taught by Mapson et al. is not used in anyway to determine whether there has been an *improper connection* with an endoscope. In this respect, leak detector 34 is connected with a leak test port 36 to check whether a lumen or other structure internal to the endoscope is leaking, e.g., whether it holds a preselected vacuum or positive pressure (see column 4, lines 24-27). It is further stated by Mapson et al. that the common control causes the leak check device to check whether the *lumen* connected with port 36 is leaking or not. Accordingly, leak detector 34 of Mapson et al. is used

as a means for determining whether there is a problem *internal to the lumen*, and not whether there is an improper connection between the lumen and an external port.

Mapson et al. insure that the proper leak detector and anti-microbial fluid ports of a disinfection or sterilization system are interconnected with the proper lumen ports of an endoscope by use of a *tethered connection assembly 50* (see column 4, lines 61-67 and column 5, lines 1 *et seq.*). The tethered interconnection assembly includes fittings 60, 62, 64 that are *uniquely configured* for interconnection with an appropriate one of a high pressure port, a low pressure port, and a leak detector port. In this regard, one of the connectors 56 has a fitting 60 that is configured to *mate only with* the leak test port 36. The other end of the connector has an appropriate fitting for interconnection with the leak test port of the endoscope. Another of the connectors may have a fitting 62 that is configured to be *connected only with* one of the high pressure fluid ports 28, while other connectors have a fitting 64 configured to be *connectable only with* one of the low pressure output ports 28. Mapson et al. teach that various techniques may be utilized to limit each fitting to be connected with only specific one or ones of the ports 28, 36, such as different diameters, different connecting mechanisms (threaded, bayonet, etc.), different shapes, and alike. Moreover, the length of the tether and the length of portions of the tether between the various plugs and connectors are selected such that each of the connectors and fittings *just reach a port* of the endoscope to which they are to be connected. Thus, if one of the connectors or plugs is connected with the wrong port (i.e., an improper connection), the tether will be too short for other connectors or plugs to reach an available port on the endoscope. Mapson et al. notes that "this provides a ready indication to the operator that the plugs and fittings ***have not been connected properly or that the wrong tether assembly has been selected***." See column 5, lines 13 *et seq.* As indicated above, the tethered connection assembly 50 of Mapson et al. is even used to detect and prevent improper connection with leak test port 36. As indicated above, the leak detector associated with leak test port 36 does not provide a means for detecting an improper connection, but rather is used solely as a means for determining whether there is a leak *internal* to the lumen of an endoscope. In view of the foregoing, it is respectfully submitted that Mapson et al. actually teaches away from using pressure level detection as a means for determining proper connections.

Malkin et al.

The Examiner has cited Malkin et al. in support of the teaching that "in a flexible endoscope steam sterilization system, pressure tests can be run to determine the channels or lumens that are connected with the steam sterilant source (paragraph 48)." With reference to paragraph [0048] of Malkin et al., it is noted by Malkin et al. that a device connector may be designed to automatically close or open individual tubing conduits or outlet ports. Closing or opening of tubing conduits or outlet ports may be controlled by a central processor. Malkin et al. also notes that alternatively, a system connector and a medical device may be designed so that coupling of the system and connector can automatically *result in the proper conduits or ports being opened or closed,* by providing actuating structure on the device with mating structure on the connector, such that when the actuating structure and the mating structure are coupled, the *appropriate* conduits or ports are opened or closed.

Malkin et al. uses the "pressure tests" described above *to determine which* ***channels or lumens*** *have been made to be in communication with a steam source of a system 10* so that steam can be *selectively flowed* through the connected channels or lumens sequentially, alternating, for different durations, or with different heat content. However, nowhere does Malkin et al. teach or suggest using a pressure test as a means for determining whether there has been an *improper connection* between the steam unit and the channels or lumens. Nor does Malkin et al. provide any means for *identifying and correcting the improper connection.* Malkin et al. only teaches identification of channels or lumens connected to the steam source so that appropriate operating parameters (e.g., duration, or heat content) can be used when flowing steam through the connected channel or lumen. It is the *internal* channel or lumen of the medical device that is being identified, not whether the medical device is *properly connected* with the steam source. Malkin et al. are not concerned with identifying or correcting an improper connection between the medical device and the steam unit.

The Examiner has concluded that in view of Weber et al., Mapson et al., and Malkin et al. that:

> it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pressure sensor in

> Weber et al.'s invention to determine if there is an improper connection between the medical instrument and the sterilant ports because an improper connection would lead to fluid pressure and sterilant loses, thereby increasing the expense to operate Weber et al.'s reprocessor apparatus. Additionally, a proper connection could have been beneficial to Weber et al.'s reprocessor because it would have further insured that medical instrument sterilization was complete by leaving no part of the instrument contaminated as taught by Mapson et al. above, which is a concern since Malkin et al. teach the complexity of the inner parts of endoscopes (paragraph 8).

In view of the foregoing discussion of each of the cited references, it is respectfully submitted that none of the cited references provides a motivation to one skilled in the art to use a pressure sensing means for sensing the pressure of fluid flowing through a fluid circulation system and a controller for determining whether the sensed pressure is indicative of an improper connection with the device being microbially deactivated, as required by independent claim 1. As discussed at length above, each of the cited references have deficiencies, and none meets the limitations set forth in independent claim 1.

Moser

The Examiner has relied upon Moser for teaching a sterilization system for endoscopes in which endoscope ducts are checked for clogs. The Examiner notes that when a clogged duct is determined, the specific duct is indicated on a display field of a control unit (column 6, lines 15-18). The Examiner concludes that:

> it would have been obvious to one having ordinary skill in the art at the time the invention was made to display the location of an improper connection found in Weber et al.'s reprocessor apparatus on the screen display just as the clogged duct location was displayed in Moser's invention to notify the user of which connection is improper so the connection can be made proper, thereby increasing the response time for operators to make the reprocessor safe from spilled sterilant. This would have also aided in preventing the shutdown of all the reprocessors at once to correct the connection, since Weber et al. teach that all four reprocessors could be controlled and monitored simultaneously (column 8, lines 22-26).

The "improper connection" recited by claim 1 of the present application refers to an improper connection with the device being microbially deactivated, not a defect *internal* to the device being microbially deactivated, as in Moser. In this regard, Moser teaches indication of a clogged endoscope duct on a display field of a control unit. Moser's apparatus determines that an endoscope duct is not clogged when air flows through the endoscope duct via a float body magnet switch. If a given duct is determined to be clogged, the magnetic switch is not released. As a result, the clogged duct is indicated on a display field of the control unit, and the machine is stopped (see column 6, lines 9-18).

It is respectfully submitted that detecting and displaying the location of a clogged duct within the device being microbially deactivated is not equivalent to determining whether there is an improper connection with the device being microbially deactivated, and displaying a graphic indicating the location in the reprocessor apparatus where the improper connection with the device has been detected. The detection of a "clogged duct" does not provide an indication as to whether a device being microbially deactivated has been properly connected. Likewise, a proper connection with the device being microbially deactivated does not provide an indication as to whether an endoscope duct is clogged.

Moreover, a clogged duct will exhibit significantly different characteristics than an improper connection with the device. In this regard, a clogged duct will likely result in an increase in pressure, whereas in improper connection with the device is indicated by a sensed pressure that is "lower than a pressure value associated with a proper connection with the device," as now recited in independent claim 1. Moser is concerned with a condition *internal* to a device being microbially deactivated, rather than the connection between the fluid circulation system and the device being microbially deactivated.

As discussed above, claim 1 has been amended to incorporate limitations of claims 3 and 9. The limitation of claim 3 (now incorporated into claim 1) defines the graphic displayed by the display unit as including "a visual indicator providing information for *correcting* the improper connection." The Examiner has previously rejected claim 3 based upon the teachings of Malkin et al. In this regard, the Examiner argues that Malkin et al. teaches "that the central processor responds with error messages, status notifications, and alike at the user interface display (paragraph 80)." Accordingly, the Examiner concludes that "it would have been

obvious to one having ordinary skill in the art at the time the invention was made to display corrective actions on the display screen of Weber et al.'s invention to aid hospital users who are new to using the reprocessor apparatus in correcting a connection problem, which, as Malkin et al. teaches, would contribute to faster-acting sterilization (paragraph 11)."

First, it should be noted that Malkin et al. fail to teach or suggest a specific visual indicator that is used for correcting an *improper connection* between a fluid circulation system and a device being microbially deactivated. Neither error messages nor status notifications teach or suggest the "visual indicator" as now defined by claim 1. Furthermore, the Examiner appears to look to paragraph [0011] of Malkin et al. for motivation to combine the teachings of Weber et al. and Malkin et al. However, the "fast-acting sterilization method" referenced in paragraph [0011] appears to refer to the process steps of a sterilization cycle, and not process steps outside the sterilization cycle, such as those used to correct an improper mechanical connection. In particular, it is believed that the "fast-acting sterilization method" refers to the speed by which a sterilization cycle can be completed.

As the Examiner is well aware, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since the Examiner is relying upon four (4) different prior art references, the Examiner must provide appropriate suggestion or motivation to combine various teachings from all four references. It is respectfully submitted that the requisite prior art suggestion to combine becomes less plausible when the necessary elements can only be found in a large number of references.

Moreover, it is respectfully submitted that none of the cited references, even if taken in combination, teaches or suggests the applicants' invention as set forth in the present claims. As discussed at length above, none of the cited references, with the exception of Mapson

et al., is directed to detecting whether a proper connection exists between a fluid circulation system and a device being microbially deactivated. In this respect, Weber et al. is concerned with detecting pump failure for a pump supplying fluid to a manifold; Malkin et al. is concerned with determining which of a plurality of *internal* channels or lumens of a device are in fluid communication with a steam source in order to flow steam selectively through the internal channels or lumens; and Moser is concerned with detecting clogs within *internal* endoscope ducts. While Mapson et al. is admittedly concerned with proper connections, it teaches away from using pressure sensing as a means for detecting and preventing improper connections. Instead, Mapson et al. relies upon the physical characteristics (i.e., dimensions and shapes) associated with a tethered connection assembly to detect and prevent improper connections.

It is respectfully submitted that none of the cited references, taken individually or in combination, teaches or suggests a monitoring system as defined by independent claim 1 requiring a pressure sensing means for generating an electrical signal indicative of the sensed pressure; a controller, responsive to the electrical signal, for determining whether the sensed pressure is indicative of an improper connection with the device being microbially deactivated; and a display unit for displaying a graphic indicating a location in the reprocessor apparatus where the improper connection with the device has been detected, wherein said graphic includes a visual indicator providing information for correcting the improper connection.

In view of the foregoing discussion, it is respectfully submitted that a *prima facie* case of obviousness is not supported in view of the teachings of Weber et al., Mapson et al., Malkin et al., and Moser. Accordingly, it is respectfully requested that the Examiner withdraw the prior art rejection of claim 1, and claims 4-8 that depend therefrom.

The applicants respectfully submit that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8724US.

Respectfully submitted,

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